

Statement on the Importance of Home Respiratory Therapy in Response to Immediate and Long-Term Needs of Patients Due to the COVID-19 Pandemic

*Prepared for the Subcommittee on Health,
Committee on Energy & Commerce, U.S. House of Representatives for
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“The Long Haul: Forging a Path through the Lingering Effects of COVID-19.”*

The Council for Quality for Respiratory Care (CQRC) wants to thank the Subcommittee for holding today’s hearing and focusing on the lingering effects of COVID-19. We appreciate the Congressional support for health care providers and suppliers during the COVID-19 pandemic. Home respiratory therapies, including home oxygen, sleep, and non-invasive ventilation therapies, continue to play an essential role in the recovery of many patients with COVID-19. For some COVID-19 patients, the long-haulers as they are known, these home respiratory therapies have become an essential daily treatment.

The CQRC is a coalition of the nation’s six leading home oxygen and sleep therapy providers and manufacturing companies. Together, our members provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare beneficiaries who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment, and supplies to more than one million Medicare beneficiaries with Obstructive Sleep Apnea (OSA).

During the pandemic, CQRC members have been on the frontlines of the battle against COVID-19. They have experienced an increase in acute patients and fluctuations in the number of chronic patients, leading to shortages in equipment and supplies, and rising costs. As the pandemic moves into its second year, a significant percentage of patients continue to experience respiratory conditions that require their ongoing reliance on home respiratory therapies. However, Medicare has not yet committed to retaining the flexibilities that allowed these patients access to home respiratory therapies during the pandemic. These flexibilities are also important to rebuilding the home respiratory sector, which have been significantly weakened by years of flawed reimbursement, documentation, and audit policies.

I. Overall Increase in Acute Patients Needing Home Respiratory Therapy

The first challenge home respiratory suppliers and manufacturers have faced during the pandemic is the increasing demand for home respiratory therapies. This challenge continues today. In general, patients with chronic respiratory conditions have been less likely to seek medical help, putting off early screenings and health care visits out of fear of COVID-19. Based on data from the CQRC members, the number of patients with chronic

respiratory diseases seeking home therapies fell, especially during the first part of the pandemic. Yet, the percentage of patients with acute conditions, including those with COVID-19, increased by more than 229.46 percent, based on CQRC company data. These patients included those with conditions, like pneumonia, as well. Generally, Medicare will not cover home oxygen for acute patients, but it did extend coverage during the pandemic to allow these patients to recover at home instead of in a hospital. The percentage of new start acute patients in Medicare increased by 229.46%, while the percentage of new start chronic patients in Medicare decreased by 25.10%. These trends have continued as different surges of infection and hospitalization have spread across the United States.

These statistics were true for the general population as well. Data from “hot spot” states echoes this pattern. There is a substantial increase in acute patients and a substantial decrease in chronic patients.

State	Acute Patients Percent change Jan-June 2020	
	All payers	Medicare
Arkansas	220.90%	347.83%
California	299.12%	360.87%
Florida	166.22%	167.31%
Georgia	319.05%	210.96%
New Jersey	266.67%	159.38%
New York	82.95%	242.31%
Texas	251.45%	159.38%
Washington	80.12%	186.36%

This shift in treatment options has put a tremendous strain on the home respiratory sector.

II. Increases in Demand Have Led to Shortages

Because of the effects of COVID-19, the World Health Organization warned of an oxygen equipment shortage in 2020. As the media has reported, those warnings came true with shortages throughout the United States and around the world. During various times in the pandemic, CQRC companies have seen up to 45% of their oxygen new equipment orders from manufacturers being cancelled or backlogged. They experienced similar problems with positive airway pressure devices/respiratory assist devices, and nebulizers.

The shortages have resulted from a worldwide increase in demand for oxygen equipment and supplies, ventilator equipment and supplies, nebulizers, and positive airway pressure products. For example, for one manufacturer, demand for oxygen concentrators has doubled since the beginning of the pandemic. Manufacturers are experiencing problems obtaining common components like resin, resistors, and printed circuit boards. This problem has also strained access to proprietary parts manufactured for several products. To meet increased demand, manufacturers are experiencing increased component, manufacturing, and freight costs, some of which are passed along to customers.

In addition, other organizations that do not traditionally purchase oxygen equipment, such as prisons, are now doing so. Other providers, such as hospitals, that may have purchased oxygen on a more limited basis have increased their demand substantially as well. These additional purchasers have further strained access to respiratory therapy devices for patients in the home.

III. Increases in Costs

In addition, CQRC members, like other health care providers, have experienced supply chain problems, increased costs for personal protective equipment, and difficulties with vaccinating their employees who enter patients' homes. As a result, the cost of providing equipment and services to patients has risen to levels that exceeded anyone's expectations. While all of us had hoped that the pandemic would have ended by now, the reality is that it is likely to continue for some time. The economic challenges facing health care providers and suppliers will also likely remain in place at least through the duration of the PHE.

IV. Supporting a Sustainable Home Respiratory Therapy Infrastructure

As reported in the media, the changing demand, exponential increase in the need for home oxygen in "hot spots," and shortages of equipment have illuminated the systemic problems home respiratory therapy patients, suppliers, and manufacturers have faced for several years. The driving factor for these problems has been a flawed set of Medicare policies. As the dominant payer for chronic respiratory patients, Medicare policies have a disproportionate impact on the health of this sector. The Medicare competitive bidding program historically used a methodology that forced suppliers to accept rates below their bid amounts (and by extension costs). The result of this unfair system led to hundreds of suppliers leaving the business prior to the pandemic. It also led to the loss of access for certain types of equipment (such as liquid oxygen), limited access in rural areas, and a substantial reduction in the services suppliers could provide. In addition, it resulted in a stagnation in innovation in the areas of home respiratory products. Innovators have avoided working in areas of health care where they cannot recover their research and development costs.

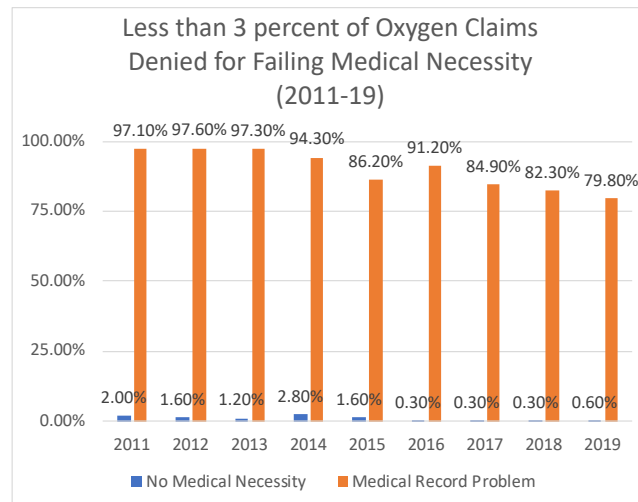
With these problems unresolved, the pandemic hit the United States. The CQRC applauds the Congress and the Centers for Medicare & Medicaid Services (CMS) for acting quickly and implementing important policies that provided temporary relief. These policies included providing reimbursement increases in non-competitive bidding areas and removing the out-of-date budget neutrality requirements on home oxygen reimbursement. The Congress also has provided sequestration relief. CMS reduced the documentation and audit requirements. These steps eliminated barriers facing patients who required home respiratory therapy, especially those with COVID-19. Together, the Congress and CMS also expanded telehealth options to allow patients to access their health care providers remotely.

During the pandemic, the CQRC members have stepped up to meet the challenge, but they require help to be able to maintain the services needed today and to be prepared for potentially emerging new diseases. They especially need federal help to maintain the flexibilities implemented during the pandemic to create long-term reimbursement stability, simplify documentation requirements, and reduce unnecessary audits. In brief, the CQRC requests:

- **Grandfathering Beneficiaries Who First Received Home Respiratory Therapy During the COVID-19 Pandemic.** During the pandemic, the number of patients who required home oxygen therapy for acute conditions like COVID-19 increased substantially. Some “long-hauler” patients continue to require home oxygen. CMS rightly waived certain documentation requirements to make sure these patients received the therapy they needed. Once the pandemic public health emergency (PHE) ends, it will be important to streamline the documentation requirements to make sure that these patients continue to receive the therapies they need. We suggest grandfathering Medicare coverage for these patients so they do not have to relinquish their equipment or have additional copayment obligations.
- **Stabilizing the Reimbursement Rates for Home Respiratory Therapies.** Rates in rural areas are set at the urban competitive bidding rates plus 10%. These rates are dramatically below the cost of providing services to beneficiaries in these areas. The Congress provided relief to rural rates during the pandemic by setting the rates at 50 percent of the fee schedule rates + 50 percent of the competitive bidding adjusted rates. In the CY 2021 DMEPOS Fee Schedule rural rates, CMS proposed making this blended rate permanent, but has yet to finalize the rule. Finalizing this proposed rate modification is critically important to maintaining access to home respiratory treatments in rural America.
- In addition, CMS has removed most product categories from the Round 2021 competitive bidding program. While there were some anomalies in some of the product areas in some competitive bidding areas, the rates that would have been set were higher than the previous round rates. This outcome was expected, even by the CMS actuary, because the previous methodology was so flawed, as described in detail by the Pacific Research Institute in 2018.¹ The CQRC believes it is important to create a stable reimbursement system to allow for much needed predictability, which was lost because of the downward spiraling of rates created by the median bid methodology of the previous competitive bidding program. Stability and predictability are essential to rebuilding the home respiratory therapy sector to support the long-haul patients and to be prepared for the next public health crisis.

¹Winegarden, Wayne. “Medicare Competitive Bidding Process Should Be Reformed.” Pacific Research Institute. (2018) available at <https://www.pacificresearch.org/new-study-medicare-competitive-bidding-process-should-be-reformed-to-improve-health-outcomes-ensure-patient-access-to-medically-necessary-equipment/?platform=hootsuite>.

- **Stopping Medicare from Second-Guessing Physician Prescriptions.** During the pandemic, patient medical records were secondary to patient care. Prior to the pandemic, home respiratory therapy suppliers battled an overwhelming number of audits that result in claim denials, which Administrative Law Judges ultimately reinstated. As the chart below shows, the vast majority of these denials were due to insufficient wording in physician medical records.



Medicare coverage policy establishes objective criteria that do not require the medical record to determine medical necessity. Yet, the contractors insist on suppliers getting individual patient's confidential medical records from their physicians to "confirm" that the objective, independent test results the physician ordered are consistent with the physician's notes. Medicare should stop this game of "gotcha" by eliminating the requirement for contractors to review individual patients' medical records for home respiratory therapies or establish prior authorization process for home respiratory therapies.

While these policies are directed toward Medicare, they will also help support access to home respiratory therapies for all patients. Commercial insurers often look to Medicare policies as the basis for their own. Thus, addressing barriers to access in Medicare can have a positive effect for patients of all ages.

V. Conclusion

As the United States moves into its second year of the COVID-19 pandemic, there is hope for many with better treatment options and vaccines becoming more widely available. Yet, the crisis is not over. Many Americans remain unvaccinated. Mutations raise questions about whether new vaccines will need to be developed. We cannot predict how many more Americans will be infected and experience serious illness, hospitalization, and death. And, for some Americans, their battle with COVID-19 may never end.

The CQRC remains committed to working with federal, state, and local officials to make sure that COVID-19 patients and those with other chronic respiratory diseases have access to home respiratory therapies that reduce overall health care spending by preventing hospitalizations and readmissions. For these patients and in preparation for the next public health emergency involving a respiratory disease, it is important that the Medicare program provide a sustainable payment system that focuses on patient medical needs over paperwork and protects against fraud and abuse in a balanced and fair manner.

The CQRC looks forward to working with the Subcommittee to make sure that when Americans need home oxygen, sleep, or non-invasive ventilation therapies they are able to access these life-sustaining treatment options.